

Application No. 10/511,885  
AMENDMENT  
Reply to Office Action of March 17, 2009

### REMARKS

#### Introduction

Claims 1-11, 13-21, 23-44 are pending in this application. Of the pending claims, claims 1, 6, 34, 36, 38, 43 and 44 are independent claims. Dependent claim 17 has been cancelled. Independent claims 1, 6, 34, and 36 have been amended and independent claims 43 and 44 are new.

#### The Art Rejections

All of the art rejections are based upon obviousness. The Examiner rejected all claims as obvious over Geiss (U.S. 2004/0120985) in view of Kiliaan et al. (WO 01/84961).

The Examiner rejected claim 32 as obvious over Geiss (U.S. 2004/0120985) in view of Kiliaan et al. (WO 01/84961) and further in view of De Simon et al. (U.S. 2002/0031507).

#### The Non-Art Section 112 Rejections

The Examiner rejected pending claims 1-11, 13-21 and 23-37 under 35 U.S.C. § 112, first paragraph written description requirement, because the independent claims are purportedly not supported by the specification as these claims do not recite various components as supporting material

The Examiner also rejected pending claims 1-11, 13-21, and 23-33 under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner rejected the independent claims because of the way applicants express the weight percentage of phospholipid components.

#### The Obviousness Type Double Patenting Rejection Is Obviated

Applicants are filing a terminal disclaimer which addresses and solves this rejection.

Application No. 10/511,885

AMENDMENT

Reply to Office Action of March 17, 2009

Applicants Provide A Matrix Which Stabilizes A Phospholipid Components So Increased Amounts Of The Latter Components Are Delivered To A User, Even With Foods Where The Phospholipid Could Not Be Added.

At page 6 (top paragraph) of the specification in this application, applicants state:

Surprisingly the claimed special foods not only have additional beneficial health properties according to the object, but moreover make it possible to make new functional foods and specialized foods which are characterized by the special stable matrix. Thus it is for example possible to use the matrix to incorporate phospholipids into foods to which these exogenous additives could previously not be added due to hydrolysis and oxidation. In particular it is now possible to simply and stably enrich fermented milk products and drinks in general, cereals in the form of flakes and extruded products with phospholipids. Thus most of these advantages were not predictable. (Emphasis added)

Applicants in their specification in this application make it clear that there is an enhanced amount of phospholipid component forms part of the matrix and comprises  $\geq 5$  weight %, and in preferred form  $\geq 15$  weight % of the matrix. See page 7, second paragraph and claims 1 and 15, as filed. Thereafter the specification in this application states, "it is now possible to stably incorporate phospholipids over long periods into media which were previously not accessible due to example to oxidative or hydrolytic effects or because of pH and solubility problems." See page 10, end of second full paragraph. Hence the specification describes a high loading of phospholipids as part of a matrix where the phospholipids enjoy enhanced stability.

Additionally, the matrix made be made with the phospholipids as a part of a large or master batch of a matrix. This allows for the supply of phospholipids in a stable form that avoids hydrolysis and oxidation.

The References

1. Geiss et al.

Geiss et al. disclose a food item for enhancing cognitive capacity. Although Geiss et al. disclose a composition comprising carbohydrates, proteins, phosphatidylserine, vitamins and fat, Geiss et al. do not teach any matrix which is suitable for stabilizing the phospholipids or a matrix with enhanced amounts of a phosphatidyl component. Indeed Geiss confirms this fact with his examples. These examples clearly show a reduced amount of phosphatidyl component in Geiss' food products compared to the minimum amounts of phosphatidyl component required by the claims. Geiss does not have a phosphatidyl component combined with a support such that the phosphatidyl component is stabilized and can be delivered in the food product in large amounts as a part of a stabilized matrix. Indeed, Geiss only delivers relatively small amount of phosphatidyl component (as opposed to a large phosphatidyl content as described in the instant application). Geiss' specification proves this point.

[0020] ....The minimum quantity of carbohydrates is preferably 15 g combined with preferably 100 to 300 mg of phosphatidyl serine.

[0021] Preferably, the new food product according to the present invention has the form of a bar, preferably a chocolate bar. The nutrient-physiological active ingredient in the bar is phosphatidyl serine, preferably made from a lecithin extract containing phosphatidyl serine.

[0022] In addition, the bar preferably has a relatively high carbohydrate content so as to ensure the desired combination effect of a short-term improvement of the cognitive functional capacity after consumption of phosphatidyl serine. The carbohydrate content should be higher than 40 wt %, preferably higher than 57 wt %. This corresponds to a content of more than 1 wt %, preferably 1.4 wt %, of lecithin extract containing phosphatidyl serine.

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[0052] The ingredients per 100 g of the chocolate bar are: fructose syrup, sugar, powdered skim milk, cocoa butter, powdered milk, milk protein, sweet whey

Application No. 10/511,885

AMENDMENT

Reply to Office Action of March 17, 2009

powder, dextrose, hydrogenated vegetable oil, cocoa mass, maltodextrin, modified starch, rice extrudate, 1.4 g of lecithin extract, coffee extract, flavor compound, emulsifier lecithins, 120 mg of vitamin C, dried egg albumin, 13.2 [mg] of pantothenate, 13 mg of vitamin E, 8 mg of niacin, 4 mg of vitamin B1, 4 mg of vitamin B6, and 200 mg of phosphatidyl serine from lecithin extract. The product size of the bar is preferably 35 g.

At paragraph 0052 Geiss refers to 100 g of ingredients for a food bar to get his percentages and milligram weight of phosphidyl serine in paragraph 0052. He is saying in his 100 g mix, you will get 200 mg of phosphatidyl serine.

Going back to paragraph 0022, one sees that the carbohydrate content of Geiss' product runs from 40 to 57 weight %. Going back to paragraph 0052, this means that the low and high end of carbohydrates content is 40 g and 57 grams. In the instant application a matrix can be a carbohydrate, this means that at the low end the matrix will be 40.2 g or at the high end 57.2 g. Then the phosphatidyl serine will be a percentage of the carbohydrate + phosphatidyl serine which will range from  $0.2/40.2$  to  $0.2/57.2$  or 0.4975% to 0.3496%. True, there may be other materials which Geiss has which could go into our matrix, but that would make the percentages of serine even lower! Further, even if did these calculations using the max amount of serine (300 mg), the percentages may go up a little, but the percentage of the matrix is still very, very small.

Geiss does not suggest the high phosphatidyl content or phosphatidyl stabilization as required and described by the instant application. Indeed Geiss aims at supplementing a diet with phosphatidylserine, and in view of this goal, a person of ordinary skill would only include only small amounts of a phospholipid into a chocolate bar as discussed by Geiss. Hence, Geiss does not remotely suggest or solve the problem recognized and solved by the instant application.

2. Kiliaan

Kiliaan et al. describe a composition for the treatment of vascular disorders. The composition has three components, namely a long-chain polyunsaturated fatty acid, a phospholipid component and a further component which is a factor in methionine metabolism. In Kiliaan's Example 5, Kiliaan merely mixes ingredients and does not create a matrix of (i) a supporting material selected from the group consisting of carbohydrates, proteins, hydrophobic materials, hydrophobic polymers, mineral components, and mixtures thereof, and (ii)  $\geq 5\%$  by weight of an acetone-insoluble phospholipid component.

Kiliaan is distinguished because (1) "consisting of" (see independent claim 1) excludes one of that reference's active components, the factor in methionine metabolism; and (2) Kiliaan never describes stabilizing the phospholipid as a part of a matrix (the phospholipid on a support) as opposed to just mixing up ingredients which would not necessarily put the phospholipid onto the supporting material.

The Combination Of Geiss and Kiliaan Does Not Suggest The Claimed Invention

Geiss does not suggest a stabilizing matrix. Indeed Geiss only has low amounts of a phospholipid component. Kiliaan does not suggest a matrix of supporting material and a phospholipid component. The combination does not suggest the claimed invention.

The Rejection Under Section 112, First Paragraph, Has Been Obviated.

In this rejection the Examiner has asserted that the claim lacks support because it does not specifically recite the components that constitute the support. The specification provides an abundant written description of specific items which can be used for the support. Page 8 of the specification of the instant application provides in pertinent part,

Application No. 10/511,885

AMENDMENT

Reply to Office Action of March 17, 2009

(Un)-modified carbohydrates and proteins, hydrophobic materials such as waxes, triglycerides, lipids and polymers or mineral components such as silicates and mixtures thereof have proven to be particularly suitable as supporting materials of the stable matrix. The lipids can be hydrogenated or have a special composition; the polymers can be pharmaceutical polymers and/or polymers suitable for foods. In this connection, cereal products such as maize, wheat, oats, rice etc. deserve particular mention which represent typical supporting materials as flakes or extrudates.

In order to take the respective matrix forms and applications into account, the invention envisages that in particular starch (derivatives), mono- and disaccharides and their sugar alcohols, glucose syrup, dextrins and hydrocolloids such as alginates, pectins, chitosan and cellulose (derivatives) are used as representatives of the carbohydrates. Particularly suitable representatives of proteins are plant, animal and microbial proteins such as zein, gluten, gelatin, casein, whey proteins or mixtures thereof and also single-cell proteins and texturized proteins such as spun or extruded (soya) protein isolate.

Applicants respectfully submit that the above portion of the specification more than adequately supports independent claims 1, 6, 34, 36, 38 and 43. Applicants also call the Examiner's attention to dependent claims 13 and 14 which depend from or ultimately depend from claim 1 specifically name support components and show that the independent claims meet the written description requirement. Certainly these dependent claims should be allowable in view of applicants' disclosure.

Applicants also call the Examiner's attention to added dependent claims which depend from independent claim 38 which specifically name support components. These independent claims should be allowable in view of applicants' disclosure.

Even further applicants have added independent claim 43 which adds Markush groups specific components disclosed for the support material. This independent claim should be allowable in view of applicants' disclosure.

Application No. 10/511,885  
AMENDMENT  
Reply to Office Action of March 17, 2009

The Rejection Under Section 112, Second Paragraph, Has Been Obviated.

The claims have been amended to clarify that the amount of acetone insoluble phospholipid component is based upon the total weight of the matrix. This is supported by the fact that the matrix starts from a support and an acetone-insoluble phospholipid component (see page 7, third paragraph of the specification) and the weight percent of the phospholipid component is based upon the total weight of the matrix. The examples also support the amendment.

With respect to the Examiner's assertion that the word "stable" is unclear or indefinite, applicants call the Examiner's attention to the specification. At page 6 the specification states:

Surprisingly the claimed special foods not only have additional beneficial health properties according to the object, but moreover make it possible to make new functional foods and specialized foods which are characterized by the special stable matrix. Thus it is for example possible to use the matrix to incorporate phospholipids into foods to which these exogenous additives could previously not be added due to formulation problems and also due to the sensitivity of the phospholipids to hydrolysis and oxidation. In particular it is now possible to simply and stably enrich fermented milk products and drinks in general, cereals in the form of flakes and extruded products with phospholipids. Thus most of these advantages were not predictable.

At page 11 the specification states,

The matrix forms contained in the claimed functional foods and specialized foods are particularly advantageous forms of administration for the said special food forms due to their special features such as diameter, coat or capsule core since they can be produced in many different forms and thus cannot only be adapted to the needs of the consumer but also impart additional positive properties to the conventional special foods which relate not only to the physiological effectiveness of the entire food and the added matrix but also to the possibility of for example completely or partially pigmented, aromatizing and/or specially shaping the matrix. In this manner it is now possible to stably incorporate phospholipids over a long period into media which were previously not accessible due for example to oxidative or hydrolytic effects or because of pH and solubility problems.

Applicants respectfully submit that the word "stable" in view of the specification does not make the claims indefinite.

Applicants respectfully call the Examiner's attention to claim 1 which describes a supporting material; hence, there is support for the same phrase in claim 15 from which claim 15 ultimately depends.

Geiss Does Not Combine With DeSimone To Support The Rejection Of Claim 32

Geiss seeks to supplement diet, and specifically the positive effect that phosphatidylserine has on brain function. This specific effect can not be achieved by sphingomyelin disclosed in DeSimone. Hence, a person of ordinary skill would not replace the phosphatidylserine in Geiss with the sphingomyelin disclosed in DeSimone. In short, without using applicant's specification as a roadmap, a person of ordinary skill would not combine the references.

Conclusion

Claim 1 includes "consisting of" and eliminates the methionine metabolism component required by Kiliaan. Also Kiliaan does not suggest a matrix. Geiss and Killian do not suggest the matrix as described in the independent claims, nor does the Geiss/Killian combination remotely suggest a food product comprising a phospholipid-containing stable matrix comprising (i) a support and (ii)  $\geq 5\%$  by weight an acetone-insoluble phospholipid component applied to the support.

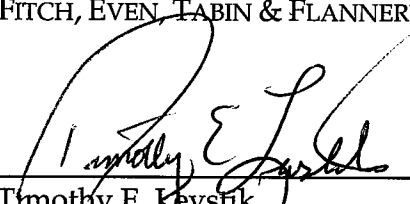
Application No. 10/511,885  
AMENDMENT  
Reply to Office Action of March 17, 2009

The Commissioner is hereby authorized to charge any additional fees which may be required in this application under 37 C.F.R. §§1.16-1.17 during its entire pendency, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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